



# Lab-O-ratory

North Carolina  
NC Department of Health and Human Services • State Laboratory of Public Health

**LAB-ORATORY, April 2001**

**Number 79**

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## **Public Health Month and National Medical Laboratory Week**

April is Public Health Month! The National Medical Laboratory Week also falls in April, this year during April 15-21. This is an excellent time to recognize the contributions of State Public Health Laboratories. These laboratories offer more than just clinical testing. Public Health is about prevention, monitoring and control of agents in order to protect the public's health. There are 11 core functions and capabilities of state public health labs. These include Disease Prevention, Control & Surveillance, Environmental Health & Protection, Integrated Data Management, Food Safety, Reference & Specialized Testing, Laboratory Improvement & Regulation, Emergency Preparedness, Public Health Related Research, Training & Education, Partnerships & Communication and Policy Development.

State Public Health Laboratories provide accurate results for the assessment and surveillance of infectious, communicable and chronic diseases. These include newborn screening and testing for rabies and viral diseases, including influenza, just to name a few. These laboratories also serve as a reference lab for hospitals and other facilities. An emerging role is providing laboratory support as part of a state and national plan for natural disasters and bioterrorism response. Laboratory tests are conducted by the clinical and environmental laboratories to protect the public's food and water supply. These labs offer tests to detect food borne outbreaks and water quality. Laboratory training provides an opportunity for improving technical skills as well as offering continuing education in a rapidly changing environment. Public Health Laboratories work in conjunction with private providers to ensure the protection of the public's health. The laboratorians who provide these services should be recognized for their dedication and involvement for the community. Especially during this month, please thank these professionals for some things we take for granted: clean water, clean air, and protection from disease.

## **North Carolina State Laboratory of Public Health Prepares for Response to Bioterrorism**

The role of an effective laboratory system cannot be overstated when major events involving infectious agents occur. The laboratory plays a critical part in identifying the infectious agent and often the sources and vectors involved. Laboratory data are invaluable in helping the epidemiologists in their surveillance and tracking activities, delineating the epidemic, and managing the outbreak. Quick and accurate laboratory testing may prove to be especially important in the event of a bioterrorist attack.

With this in mind, the Centers for Disease Control and Prevention (CDC) has been working since 1999 with appropriate organizations to develop and implement a plan for a multi-level national network of laboratories able to rapidly and accurately identify the most probable agents of a bioterrorist threat or attack. Under this plan local and state public health laboratories should be able to accept, test, and/or transfer specimens to appropriate facilities where diagnostic or confirmatory testing can be performed. Four levels of laboratories have been designated to address bioterrorism sample testing: A, B, C, and D and they are characterized as follows:

- Level A Laboratory: These are public health and hospital laboratories with biosafety facilities (certified Biological Safety Cabinet as a minimum). These laboratories have the ability to rule out specific agents and to forward organisms or specimens to higher-level laboratories.
- Level B Laboratory: These are state and local public health agency laboratories with BSL-2 biosafety facilities but which incorporate BSL-3 practices and maintain the proficiency to adequately perform confirmatory testing and characterize drug susceptibility. These state and local public health agency laboratories have the ability to rule in specific agents and to forward organisms or specimens to higher-level laboratories. BSL-3 facilities are recommended but not required.
- Level C Laboratory: These are advanced capacity laboratories with BSL-3 facilities and proficiency which are sufficient to amplify, type, and perform toxicity testing. Additionally, these laboratories will evaluate reagents and tests in order to facilitate transfer for use in the Level B laboratories.
- Level D Laboratory: These laboratories can conduct all tests performed in Level A, B, and C laboratories. In addition, they can detect genetic recombinants, bank isolates, and possess BSL-3 and BSL-4 biocontainment facilities. These are highly specialized Federal laboratories with unique experience, ability to develop new tests and methods, and capability to securely maintain a bank of biologic threat agents.

It is important to remember that these laboratories all work together as members of the National Laboratory Response Network for Bioterrorism, which also includes the Department of Defense and the Federal Bureau of Investigation. In this multi-level laboratory network the A and B laboratories play an important role by ruling out the presence of bioterrorism agents when incidents occur, thus saving time and other valuable resources in the C and D laboratories. If the samples are found to contain or suspected of containing bioterrorism agents, they are sent to the appropriate level laboratory for testing.

**Bioterrorism, con't.**

The North Carolina State Laboratory of Public Health (NCSLPH) is currently preparing for its role as a Level B laboratory in the National Laboratory Response Network. NCSLPH laboratory personnel have been assigned to this activity and have attended appropriate methodology training at the CDC in Atlanta, reagents have been acquired, and laboratory protocols have been developed and, a BSL-3 facility has been created in the NCSLPH to accommodate the special handling that may be required for bioterrorism samples.

In addition to addressing the laboratory aspects of North Carolina's bioterrorism response, the NCSLPH director, Dr. Lou Turner, serves as North Carolina's coordinator for the other aspects of North Carolina's bioterrorism response plan. Some other issues to be considered in preparing an adequate response to a bioterrorism event are communication among all concerned parties, epidemiological surveillance/management, emergency medical services (including the provision of appropriate medications), and emergency management. Dr. Turner chairs the Bioterrorism Preparedness Task Force which has been established to bring representatives from all these areas together. Training exercises and mock bioterrorism events have been carried out in an effort to assess current capabilities and bolster the network as necessary. These ongoing activities and exercises will provide the best possible response to a bioterrorism event, should the need arise.

John C. Sheats, MSPH  
Deputy Director

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**CLIA NOTES:**

As in the last column, I'll try to use this opportunity to discuss a problem that we see in many laboratories, and hopefully provide some information that will make it easier to comply with the CLIA regulations.

Many of you perform various types of bacteriology testing in your laboratory, and, as you know, it is very different from the other testing you perform. Cultures are especially different because they may take several hours, or even several days, to get the final result. Herein lies the problem.

The regulations say that test records must include "...records and dates of all specimen testing...". This means that all testing performed between collection and finalizing should be documented with the date and the identification of the testing personnel. This includes "no growth" intermediate readings.

The regulations do not address where the records must be kept, but only that they must be available to surveyors. Some labs find it easier to record all their culture workup information (Gram stain, oxidase, etc.) on a log sheet or work card, while others use a report form that goes directly into the patient chart. I would encourage you to use the method that works best for you and still includes all the necessary information. Remember the idea is to be able to trace a specimen from collection through result reporting and determine everything that was done to it and by whom.

If you have any questions, please call us at our new location, the Lineberger Building on Dix Campus. The main phone number is (919) 733-1610. Each consultant has a direct line:

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Shannon Simpson  
Laboratory Consultant

**STD On-Site Assessments – A Laboratory Perspective**

In 1998 North Carolina had the dubious distinction of ranking 1<sup>st</sup> in the nation in syphilis, with 723 cases of infectious syphilis reported. In response, the NC HIV/STD Prevention and Care Branch expanded its services to offer comprehensive assessment of HIV/STD services in local health departments. As a collaborative effort, in August of 1998 the State Laboratory of Public Health Regional Laboratory Consultants were invited to join a multidisciplinary team composed of representatives from units within the HIV/STD Prevention and Care Branch (Quality Assurance, Training and Development, Field Services, and Prevention and Community Planning) to conduct these on-site assessments. With a laboratory component on the STD assessment team, the lab consultant's role has been to provide meaningful feedback to ensure the quality of testing for sexually transmitted disease (STD) specimens in local health departments.

Counties for on-site assessment are selected based on their overall rates of STDs. For comparison purposes, high and low morbidity counties with similar populations are selected for review. High morbidity is defined as exceeding the overall state rate per 100,000 (695.8/100,000 in 1998 and 673.2/100,000 in 1999) for all sexually transmitted diseases including HIV/AIDS. In 1999 a statewide Syphilis Elimination project funded by CDC was established in eight high syphilis morbidity counties. This initiative has now been included in the criteria for selecting counties each year. The Regional Laboratory Consultant for the selected county serves as the lab representative on the assessment team. Once a county is selected, dates for staff orientation and the on-site assessment are set. During orientation, introductions of the team members are made and a brief overview of the purpose and schedule for the assessment process is presented to local staff. During the assessment, tools designed by the team members are used to collect data regarding parameters such as accessibility, acceptability, availability of services, CLIA compliance, clinician practice, reporting, medical record documentation, and the HIV counseling model.

After a tour of the facility, the laboratory consultant usually begins their review of STD services by meeting with the lab manager. Issues discussed include laboratory services offered in-house, test methodologies and equipment used, CPT coding, CLIA certification, staffing and workflow, and hours of lab operation. Records that are reviewed include patient and QC logs, PT enrollment and patient charts. The laboratory consultant also reviews written lab policies and procedures governing safety, quality control, specimen collection, patient test management, equipment maintenance, and quality assurance. Time during the assessment is also allotted to the direct observation of testing practices and patient flow during an STD clinic.

After all team members have completed their interviews, manual and chart reviews, and direct observations, the team evaluates their findings and generates a written report. At conclusion of the site review, an exit meeting is scheduled with the assessment team and pertinent local staff. This meeting provides the opportunity for immediate review and feedback and identification of barriers and needs. Positive laboratory outcomes from these assessments have included identifying model policies and procedures, recommendations for improvements that have resulted in favorable CLIA inspections, and justification for additional testing personnel. Since 1998, the Regional Laboratory Consultants have participated in 19 site reviews.

**STD, con't.**

Participation in the on-site assessments has provided the Regional Laboratory Consultants a rare opportunity to spend a few uninterrupted days on site with local health department staff. The lab component of the team process highlights the connection and value of laboratory practices in the STD morbidity formula. Written responses from the agencies have been positive regarding the usefulness of the process and the recommendations and technical assistance provided.

Lisa Balance, BSMT(ASCP)  
Regional Laboratory Improvement Consultant

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***STATE PUBLIC HEALTH LABORATORY ON THE WEB...***

The State Laboratory of Public Health has been moving its data to a relational database during the past few years, first migrating the data to the State Laboratory LIMS from the less stable legacy platforms. The next challenge was providing the massive data collected by the State Laboratory on the 300,000+ patients and environmental samples, to health care providers via the web for more secure and convenient access.

With the prospect of HIPAA (Health Insurance Portability and Accountability Act) looming, the Lab had to not only base the web application on existing rules, but learn the possible impact of the impending legislation and build a system that would comply once the rules were in place. Of highest importance was security of the data.

The Laboratory has contracted with a State Convenience Contract vendor and secured the services of Steven Knesovich, the Lab's "WebMaster" to create the web application. To date, the biggest emphasis of Steven's work has been to make available on a 7 x 24 basis, laboratory results on infants tested by the State Laboratory for metabolic disorders that could lead to life impairment or even death if not treated. The pilot for this project will end April 30<sup>th</sup> at which time the Lab will open the access to all physicians and hospitals that submit specimens to the Laboratory for newborn testing. This online lookup will aid the Laboratory in limiting the 100 or more phone calls received daily for these results and provide results to physicians attending critically ill infants when the Laboratory is closed for business.

Steve has also worked with the Program Personnel in the State System who are tasked with follow-up health management of individuals and taking preventive measures to curb infectious diseases. This includes the babies with metabolic disorders, children and adults who suffer from lead exposure, victims of food borne outbreaks and other diseases. These Programs now are able to receive data while in the field and after hours. They can also download data and do statistical tabulations, as needed using whatever database tools they have competency in. Most recently, Steve has enabled the Rabies Control Program staff the ability to access test results on animals submitted for rabies by the health community. We are also working with the Vector-Borne disease unit to supply information on West Nile Virus and other viral encephalopathies via the Internet.

Future enhancements will expand the web application to provide local health departments access to results on patients tested for hepatitis, chlamydia, tuberculosis and other diseases. We will also provide the LHDs the ability to access results on public water supplies tested at the State Public Health Laboratory. There is vision that the future may allow facilities to remotely enter the demographic data on their patients and samples into the State Lab database one time, rather than filling out multiple forms to request services. Ultimately, we would like to have a paperless system to process all data transfer on patients, specimens and samples to and from the Laboratory and the medical community it serves.

Sheila Jones, Chief  
NCSLPH Information Technology Systems

**NORTH CAROLINA  
PUBLIC HEALTH MEETINGS: SPRING 2001**

<b>Meeting</b>	<b>City</b>	<b>Date</b>	<b>Contact Person/ Laboratory Section</b>
EDNCPHA	New Bern	May 2-4	<i>Ann Grush</i>
WNCpha	Asheville	April 25-27	<i>Kristy Osterhout</i>

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**WELCOME: Gwen Brown**

Gwen Brown became the supervisor of Cancer Cytology on March 1, 2001. Gwen trained at Cabarrus Hospital School of Cytotechnology in 1974 and received her ASCP registration after graduation from the program. She started work in the Cancer Cytology Unit in 1975 and has been a Quality Control Cytotech since 1983. Gwen replaces Nancy Gardner, who retired after 34 years of service to the NC State Laboratory of Public Health. Nancy has been working part time since her retirement in October. She will be missed in April when she gets to really enjoy her retirement – just in time for gardening season.

Gwen can be reached at 919-733-7146 or [Gwen.B.Brown@ncmail.net](mailto:Gwen.B.Brown@ncmail.net).

**Editorial Board**

*Brenda Webber, Cancer Cytology  
Cindy Price & Johnetha Williams, Environmental Sciences  
Elizabeth Cranford & Vickie Whitaker, Laboratory Improvement  
Kathy Benson, Microbiology  
Ann Grush, Newborn Screening/Clinical Chemistry  
Donna Jones, Virology/Serology*

**West Nile Virus Surveillance  
North Carolina State Laboratory of Public Health (NCSLPH)**

West Nile virus (WNV) was first isolated in the West Nile District of Uganda in 1937. Since that time, it has been found in humans, birds and other vertebrates in Africa, Eastern Europe, West Asia and the Middle East. It first appeared in the Western Hemisphere in New York in 1999. West Nile virus is classified as an arbovirus. In temperate climates, WNV is primarily transmitted in the late summer and early fall by infected mosquitoes taking a blood meal. While the majority of West Nile infections are asymptomatic or produce only a mild illness, this virus can cause encephalitis, an inflammation of the brain. Other arboviruses that have infected humans in North Carolina include Eastern Equine Encephalitis, LaCrosse Encephalitis, Cache Valley, Highlands J, and St. Louis Encephalitis.

Arboviral surveillance activities at the NCSLPH include testing of: mosquitoes, sentinel chicken sera, selected animal specimens and humans. Supplemental testing is provided by the Centers for Disease Control and Prevention (CDC) and other federal facilities. The NCSLPH Virology/Serology laboratory provides a diverse group of tests to detect arboviruses both prior to and after human infection. Starting in late spring or early summer, entomologists across the state collect mosquitoes and sera from sentinel chickens. This allows for mosquito control measures to be initiated immediately to decrease the occurrence of human arboviral infection. The goal is to detect West Nile virus and other arboviruses prior to human infection.

One of the best indicators of West Nile virus activity is crow death. Crow tissues are primarily tested by the United States Geological Survey (USGS) National Wildlife Health Center in Madison, WI. The first and only West Nile case in North Carolina occurred last fall in Chatham County, NC. A dead crow was identified as having West Nile virus. Citizens are advised not to handle dead crows, but to notify their local health department if they discover them.

Websites of interest include:

[www.cdc.gov/ncidod/dybid/westnile](http://www.cdc.gov/ncidod/dybid/westnile)  
[www.deh.enr.state.nc.usphpm/pages](http://www.deh.enr.state.nc.usphpm/pages)

Gina Woodlief, MS  
Medical Lab Supervisor